APR 2 5 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

TruFlow™ Long-term 12.5 French Dual-lumen Dialysis Catheters

March 27, 2003

I. GENERAL INFORMATION

Applicant's Name and Address:	Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Lisa Stone Manager, Regulatory Affairs
Common/Usual Name:	Dialysis Catheter
Proprietary Name:	TruFlow™ Long-term 12.5 French Dual-lumen Dialysis Catheters
Legally Marketed Device and Equivalence Device Comparison:	TruFlow™ Long-term 14.5 French Dual-lumen Dialysis Catheters

II. DEVICE DESCRIPTION

The catheters are long-term 12.5 French dual lumen straight polyurethane dialysis catheters with D-shaped inner lumens and a staggered tip. The catheters include a pre-attached in-growth cuff. Catheters will be offered in multi-unit packaging and with accessory components.

III. INTENDED USE OF THE DEVICE

TruFlow™ Long-term Dual-lumen Hemodialysis Catheters are indicated for use when therapy requires long-term vascular access for hemodialysis and apheresis.

TruFlow™ Long-term Dual-lumen Hemodialysis Catheters can be inserted percutaneously in the internal jugular, in the subclavian vein as required, or the femoral vein.

IV. DEVICE COMPARISON

The technological characteristics of the TruFlow™ Long-term 12.5 French Dual-lumen Dialysis Catheters are substantially equivalent to the predicate device in terms of intended use, instructions for use, material type, device specifications,

manufacturing process and method of sterilization.

V. SUMMARY OF STUDIES

A. Functional Testing

In-vitro testing was conducted on the TruFlow™ Dialysis Catheters.

Biocompatibility testing was also conducted on the catheters.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the TruFlow™ Dialysis Catheters due to their similarity in materials, design and function to the predicate device.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the TruFlow™ Dialysis Catheters function according to specifications and the materials used in the device are biocompatible. Therefore, this product is considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

APR 2 5 2003

Ms. Lisa Stone
Manager, Regulatory Affairs
Deltec, Inc.
1265 Grey Fox Road
ST PAUL MN 55112

Re: K030983
Trade/Device Name: TruFlow™ Long-term 12.5 French Dual-lumen Dialysis Catheters
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: March 27, 2003
Received: March 28, 2003

Dear Ms. Stone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

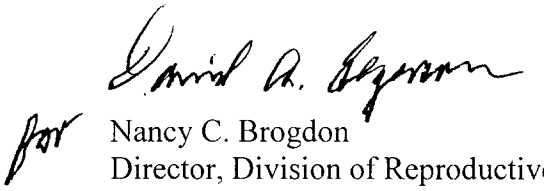
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/dsma/dsmamain.html

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030983

Device Name: TruFlow™ Long-term 12.5 French Dual-lumen Dialysis Catheters

Indications for Use:

"TruFlow™ Long-term Dual-lumen Hemodialysis Catheters are indicated for use when therapy requires long-term vascular access for hemodialysis and apheresis.

TruFlow™ Long-term Dual-lumen Hemodialysis Catheters can be inserted percutaneously in the internal jugular, in the subclavian vein as required, or the femoral vein."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030983

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)